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DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

**S & S PHARMACY, INC., d/b/a
PLATINUM PHARMACY & COMPOUNDING
DECISION AND ORDER**

On October 27, 2011, I, the Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to S & S Pharmacy, Inc., d/b/a Platinum Pharmacy & Compounding (hereinafter, Registrant), of Tampa, Florida. GX B, at 1. The Show Cause Order proposed the revocation of Registrant's Certificate of Registration as a retail pharmacy, which before it expired, authorized it to dispense controlled substances in schedules II through V, as well as the denial of any pending application to renew or modify its registration, on the ground that its "continued registration is inconsistent with the public interest." Id.

More specifically, the Order alleged that Registrant was "owned and operated by Ihab S. Barsoum," a registered pharmacist and that its registration was due to expire "on February 12, 2012." Id. The Order further alleged that Registrant's owner/operator had "unlawfully distributed oxycodone, a Schedule II narcotic controlled substance, in exchange for cash, based on fraudulent prescriptions." Id. at 2. The Order then alleged that Barsoum had made the following five unlawful distributions:

- 1) on January 24, 2011, 429 dosage units of oxycodone 30mg. and 372 dosage units of oxycodone 15mg. for \$2,500 cash;
- 2) on February 2, 2011, 1,000 dosage units of oxycodone 30mg. for \$4,000 cash;
- 3) on March 7, 2011, 2,000 dosage units of oxycodone 30mg. for \$8,100 cash;
- 4) on April 13, 2011, 700 dosage units of oxycodone 30mg. for \$3,500 cash; and

5) on June 23, 2011, 800 dosage units of oxycodone 30mg. for \$4,000 cash.

Id.

Based on the above, I further concluded that Registrant's continued registration during the pendency of the proceedings "constitutes an imminent danger to the public health and safety" and ordered that its registration be immediately suspended. Id. (citing 21 U.S.C. § 824(d); 21 CFR 1301.36(e)). Pursuant to my authority under section 824(d) and 21 CFR 1301.36(f), I authorized "the Special Agents and Diversion Investigators . . . who serve[d]" the Order "to place under seal or to remove for safekeeping all controlled substances" possessed by Registrant "pursuant to [its] registration." Id.

On October 28, 2011, the Order, which also notified Registrant of its right to either request a hearing on the allegations or to submit a written statement as to the matters of fact and law involved in lieu of a hearing, the procedure for electing either option, and the consequence of failing to elect either option, was personally served on Mr. Barsoum. See id. (citing 21 CFR 1301.43(a), (c) – (e)); GX C. Thereafter, neither Mr. Barsoum, nor any other person purporting to represent Registrant, timely requested a hearing, or submitted a written statement.

On January 25, 2012, the Government forwarded a Request for Final Agency Action along with the Investigative Record. Because more than thirty (30) days have passed since service of the Order to Show Cause and Immediate Suspension of Registration, I find that Registrant has waived its right to either request a hearing or to submit a written statement in lieu of a hearing. 21 CFR 1301.43(d). I therefore issue this Decision and Order based upon the investigative record submitted by the Government. Id. 1301.43(e).

FINDINGS

Registrant is a retail pharmacy, which is owned by Mr. Ihab (Steve) Barsoum. GX A. On October 17, 2009, Registrant was issued DEA Certificate of Registration FT0131386, which

authorized it to dispense controlled substances in schedules II through V at the registered location of Suite 204, 14937 Bruce B. Downs Blvd., Tampa, Florida, with an expiration date of February 29, 2012. GX A. According to the Agency's registration records, Registrant neither submitted a renewal application nor an application for a new registration. As a consequence, Registrant's registration expired on February 29, 2012, and on April 1, 2012, the Agency retired its registration.

The Government, however, supplemented the record with the affidavit of a Diversion Investigator, which established that on October 28, 2011, at which time the Order to Show Cause and Immediate Suspension of Registration was served on Mr. Barsoum and a search warrant was executed at Registrant, "controlled substances were seized from the pharmacy." Affidavit of DI (Feb. 2, 2012). Attached to the DI's affidavit was an inventory of the controlled substances that were seized; the inventory listed numerous controlled substances in addition to various dosage strengths of oxycodone.¹

According to the affidavit of a DEA Special Agent (S/A), in November 2010, he was contacted by a source of information who told him that he/she had previously purchased oxycodone from a person identified as Ihab Amir (Steve) Barsoum. GX D, at 4. The S/A then determined that Barsoum was a registered pharmacist and the owner of Registrant. Id. at 5.

At some point, the source of information became a confidential source (CS), and on January 24, 2011, the CS was interviewed at the Tampa DEA Office by the S/A and other Special Agents regarding text messages he had exchanged with Barsoum, in which Barsoum stated that he had 372 dosage units of oxycodone 15mg. and 430 dosage units of oxycodone 30mg. that he could sell to the CS. Id. That same day, the Agents conducted an undercover buy

¹ In addition to oxycodone, the drugs seized included, but are not limited to, morphine sulfate, methadone, hydromorphone, fentanyl, codeine with acetaminophen, hydrocodone with acetaminophen, alprazolam, clonazepam, diazepam, lorazepam, temazepam, phentermine, phendimetrazine, zolpidem, and Lyrica.

operation, using the CS to purchase oxycodone from Barsoum. Id. Prior to the buy, the CS was searched for contraband, with none found. Id. The CS was then given \$2,500 and a recording device. Id.

The S/A observed the CS travel to Registrant, enter and leave Registrant, and travel back to a neutral location, where upon arriving, the S/A received from the CS a paper bag which contained several bottles of oxycodone tablets. Id. The S/A also retrieved the recording device and searched the CS, finding the CS “free of any excess currency or contraband.” Id.

Upon counting the drugs, the S/A found 372 dosage units of oxycodone 15mg. and 429 dosage units of oxycodone 30mg. Id. The S/A also watched the video recording of the meeting and determined that Barsoum was the person who had sold the oxycodone to the CS. Id. In addition, a transcription of the recording was made and submitted as part of the record.

On February 2, 2011, a second undercover buy was conducted using the CS. Id. at 6. During the debriefing, the CS told the Agents that Barsoum had sent a text message stating that he had 1,000 dosage units of oxycodone 30mg. that he could sell to the CS and that Barsoum had also asked the CS to provide fictitious prescriptions for both the current and previous transactions. Id. After searching the CS and finding him/her to not possess any contraband, the CS was given \$4,100 in currency, a recording device, and several incomplete prescription forms. Id. The Agents then maintained surveillance as the CS travelled to and entered Registrant, as well as upon the CS’s exiting from Registrant and travelling back to meet the Agents. Id.

Upon meeting the CS, the S/A took custody of a paper bag which contained two bottles of oxycodone (which upon counting, contained 1,000 dosage units); retrieved the recording device and \$100 of unused currency; and upon searching the CS, found that the CS did not possess any contraband or excess currency. Id. at 6-7. The S/A reviewed the recording and

again observed that Barsoum was the person who had sold the drugs to the CS. Id. at 7. A transcription of the recording was made and submitted as part of the record.

On February 9, 2011, the CS contacted the S/A and related that he/she had been contacted by Barsoum, who told the CS that the prescriptions the CS had provided “were not going to work” and that the CS needed to “generate new prescription papers.” Id. at 7. Later that day, the Agents met with the CS, and upon searching the CS, determined that he/she did not possess any contraband or excess currency. Id. Thereafter, the CS was given a recording device, as well as eleven pieces of security paper, and was observed travelling to and entering Registrant, as well as upon exiting the Registrant and travelling back to meet the Agents, who again searched the CS and found that he/she had neither excess currency nor any contraband. Id.

During the meeting, Barsoum told the CS to place the name of a Tampa-area physician and the physician’s registration number, along with a working telephone number, on the fictitious prescriptions. Id. at 7-8. Barsoum then explained to the CS that the prescriptions would provide supporting documentation for the sale of the oxycodone to the CS; Barsoum also explained that the phone number would be used to show that he had called and verified the prescriptions. Id. at 8.

The following day, the Agents met with the CS, and after searching the CS, gave the CS a recording device as well as nine blank prescriptions; the CS proceeded to fill out seven of the blank prescriptions with the names of patients, their dates of birth, and the quantity of controlled substances. Id. The CS was then observed travelling to and entering Registrant, as well as upon exiting Registrant and returning to meet the Agents. Id.

According to the S/A, the CS had attempted to give all nine prescriptions to Barsoum. Id. However, Barsoum gave the two blank prescriptions back to the CS. Id. The CS explained to

Barsoum that the doctor's information including his DEA number had been placed on the prescriptions, and that the voice mail for the telephone number had been changed to "to match the new prescriptions." Id.

On March 7, 2011, the Agents again met with the CS, who informed them that Barsoum had texted him/her that he had 2,000 dosage units of oxycodone 30mg. available for sale. Id. at 9. The CS also told the Agents that he/she and Barsoum had exchanged text messages about providing fictitious prescriptions and that Barsoum needed a list of the names that were to be placed on the prescriptions so that he could enter the fictitious prescription data into Registrant's dispensing software on different days to make it appear that the dispensings had occurred on different days. Id. The CS faxed the names to Barsoum, who then sent a text to the CS acknowledging that he had received them. Id.

That same day, another undercover buy was performed. Id. After searching the CS and finding the CS to not possess any contraband, the CS was provided with \$8,100 in cash, a recording device, and several incomplete fictitious prescriptions. Id. The CS was then observed travelling to and entering Registrant, as well as exiting Registrant and traveling to meet the Agents. Id.

Upon meeting the CS, the S/A received a paper bag which contained five bottles of oxycodone, which upon counting, totaled 2,000 dosage units of oxycodone 30mg. Id. at 9-10. After retrieving the recording device and three unused prescriptions from the CS, the CS was searched and found to not possess any contraband and excess currency. Id. at 10. Subsequently, the S/A listened to the recording of the transaction and determined that Barsoum was the person who had sold the oxycodone to the CS. Id. A transcription of the visit was also made and submitted as part of the record. Id.

On April 13, 2011, the Agents again met with the CS who informed them that Barsoum had texted him/her that he had 700 dosage units of oxycodone 30mg available for sale. Id. The Agents proceeded to conduct another undercover buy. Id. After searching the CS, who was found to not possess any contraband, the CS was given \$5,000 in cash, a recording device, and five incomplete fictitious prescriptions. Id. The Agents then observed the CS travelling to and entering Registrant, as well as upon exiting Registrant and travelling back to meet the Agents. Id.

Upon meeting with the Agents, the CS turned over a plastic bag which contained one bottle of 700 oxycodone 30mg. tablets. Id. at 11. The S/A then obtained the recording device, two unused prescriptions, and \$1,500 of unused cash. Id. The CS was searched again and found to not possess any excess currency and contraband. Id. Later, the S/A listened to the recording and identified Barsoum as the person who had sold the drugs to the CS. Id. A transcription of the recording was made and submitted for the record.

On June 23, 2011, the Agents again met with the CS. Id. The CS reported that Barsoum had texted him/her that he had 1,000 dosage units of oxycodone 30mg. available for sale; however, the CS's texts to Barsoum had not been returned. Id. That day, the CS placed a phone call to Barsoum, which was recorded and monitored by the Agents; during the call, the CS told Barsoum that he was on his way to Registrant. Id. The Agents then proceeded to conduct another undercover buy.

After searching the CS and finding the CS to not possess any contraband, the CS was provided with a recording device, \$5,000 cash, and eight incomplete fictitious prescriptions. Id. The Agents observed the CS travel to and enter Registrant; they also observed the CS exit

Registrant, depart the parking lot, then immediately return and re-enter Registrant, followed by the CS again exiting Registrant and traveling back to meet with them. Id. at 12.

Upon meeting the Agents, the CS turned over a paper bag, which contained four bottles of oxycodone 30mg. tablets; subsequently, the contents of the bottles were counted and totaled 800 dosage units. Id. The S/A also retrieved the recording device, \$1,000 in unused cash, and four unused prescriptions. Id. The CS was then searched and found to not possess any excess currency and contraband. Id.

The S/A reviewed the recording and again identified Barsoum as the person who sold the oxycodone to the CS. Id. Moreover, during the course of the transaction, Barsoum told the CS to fill out four prescriptions totaling 1,200 dosage units even though Barsoum was selling only 800 dosage units to the CS. Id.

On October 26, 2011, a federal grand jury indicted Barsoum on six felony counts of violating the Controlled Substances Act. The charges included five counts of “knowingly and intentionally” distributing oxycodone “outside the course of professional practice,” in violation of 21 U.S.C. §§ 841(a)(1) and 841(b)(1)(C). GX 6, at 2-3. The indictment also charged Barsoum with one count of “knowingly and willfully conspir[ing] with other[is]” to unlawfully dispense oxycodone, in violation of 21 U.S.C. § 841(a)(1) and 841(b)(1)(C) and 21 U.S.C. § 846. Id. at 1. Finally, the indictment sought the forfeiture of, inter alia, “all of [Barsoum’s] right, title and interest in” both “property constituting and derived from any proceeds . . . obtained, directly, or indirectly, as a result of such violations,” as well as “property used and intended to be used in any manner or part to commit or to facilitate the commission of such violations.” Id. at 4-5.

On July 5, 2012, a grand jury issued a superseding indictment, which again alleged each of the conspiracy and unlawful distribution counts, as well as sought the forfeiture of the above described property. See Superseding Indictment at 1-4, United States v. Ihab “Steve” Barsoum, No. 8:11-CR-548-T-33MAP (M.D. Fla. July 2012). Barsoum pled not guilty, went to trial, and was convicted on all six counts. See Judgment and Sentence at 1, United States v. Barsoum (Feb. 5, 2013). The District Court sentenced Barsoum to 204 months imprisonment on each count, with the “terms to run concurrently,” and subsequently placed him in the custody of the U.S. Bureau of Prisons; the Court also imposed thirty-six months of supervised release following his term of imprisonment. Id. at 3-4. The Court further ordered that Barsoum “forfeit [his] interest in the following property to the United States: . . . any and all assets previously identified in the Indictment that are subject to forfeiture,” and specifically identified the property to include, but not be “limited to,” his DEA registration and two BMW automobiles. Id. at 6. Barsoum then filed a notice of appeal.

DISCUSSION

Mootness

As found above, the registration at issue in this proceeding was due to expire on February 29, 2012, and in any event, as part of its judgment, the District Court ordered Mr. Barsoum to forfeit Registrant’s registration. Moreover, Mr. Barsoum did not file either a renewal application or a new application. Accordingly, there is neither a registration to revoke nor an application to act upon.

While ordinarily these facts would render this proceeding moot, see Ronald J. Riegel, 63 FR 67132, 67133 (1998), simultaneously with the issuance of the Show Cause Order, I also ordered that Registrant's registration be immediately suspended. Moreover, pursuant to my

authority under 21 U.S.C. § 824(f), I authorized the seizure or placement under seal of the controlled substances possessed by Registrant pursuant to its registration. As found above, the Government seized an extensive inventory of controlled substances, including numerous drugs in addition to oxycodone.

Under section 824(f), “[u]pon a revocation order becoming final, all such controlled substances” which have been seized or placed under seal “shall be forfeited to the United States” and “[a]ll right, title, and interest in such controlled substances shall vest in the United States upon a revocation order becoming final.” 21 U.S.C. § 824(f). DEA has previously held that a registrant, who has been issued an immediate suspension order, cannot defeat the effect of this provision by allowing its registration to expire. See Meetinghouse Community Pharmacy, Inc., 74 FR 10073, 10074 n.5 (2009); RX Direct Pharmacy, Inc., 72 FR 54070, 54072 n.3 (2007). Thus, this proceeding presents the collateral consequence of who has title to the controlled substances that were seized and which have not been forfeited under the District Court’s judgment. Accordingly, I hold that this case is not moot and proceed to the merits.

The Merits

Under the CSA, “[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.” 21 U.S.C. § 824(a)(4). In the case of a retail pharmacy, which is deemed to be a practitioner, see id. § 802(21), Congress directed the Attorney General to consider the following factors in making the public interest determination:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

- (2) The applicant's experience in dispensing or conducting research with respect to controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Id.

“[T]hese factors are . . . considered in the disjunctive.” Robert A. Leslie, M.D., 68 FR 15227, 15230 (2003). It is well settled that I “may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether” to suspend or revoke an existing registration. Id.; see also MacKay v. DEA, 664 F.3d 808, 816 (10th Cir. 2011); Volkman v. DEA, 567 F.3d 215, 222 (6th Cir. 2009); Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I “need not make explicit findings as to each one.” MacKay, 664 F.3d at 816 (quoting Volkman, 567 F.3d at 222); see also Hoxie, 419 F.3d at 482.²

Under the Agency’s regulation, “[a]t any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to . . . 21 U.S.C. 824(a) . . . are satisfied.” 21 CFR 1301.44(e). In this matter, I have considered all of the factors and find that the Government’s evidence with respect to factors two and four, establishes that Registrant, through its owner, has committed acts which render its registration “inconsistent with the public interest.” I therefore affirm the Order of Immediate Suspension.

² In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant’s or applicant’s misconduct. Jayam Krishna-Iyer, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. MacKay, 664 F.3d at 821. Likewise, findings under a single factor can support the denial of an application.

Factors Two and Four – The Registrant’s Experience In Dispensing Controlled Substances and Compliance With Applicable Laws Related To Controlled Substances

“Except as authorized by” the CSA, it is “unlawful for any person [to] knowingly or intentionally . . . manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.” 21 U.S.C. § 841(a)(1). Moreover, “[p]ersons registered by the Attorney General . . . to manufacture, distribute, or dispense controlled substances . . . are authorized to possess, manufacture, distribute, or dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter.” *Id.* § 822(b). Under the Act, a pharmacy’s registration authorizes it “to dispense,” *id.* § 823(f), which “means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner.” *Id.* § 802(10).

Under a longstanding DEA regulation, “[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a). Furthermore, “[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”³ *Id.*; see also 21 U.S.C. § 829(a) (“Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301et seq.], may be

³ As the Supreme Court has explained, “the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006) (citing *United States v. Moore*, 423 U.S. 122, 135, 143 (1975)).

dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed . . . by regulation . . . such drug may be dispensed upon oral prescription in accordance with . . . 21 U.S.C.A. § 353(b).”⁴

As found above, on five occasions, Mr. Barsoum, Respondent’s owner and pharmacist-in-charge, offered for sale, and subsequently distributed to the CS, large quantities of oxycodone, a schedule II controlled substance (see 21 CFR 1308.12(b)(1)(xiii)), in exchange for cash. Over the course of the five transactions, Barsoum distributed a total of 4,929 tablets of oxycodone 30mg. and 372 tablets of oxycodone 15mg., in exchange for \$22,100 in cash. The distributions were not dispensings within the meaning of the CSA because the controlled substances were not delivered “pursuant to the lawful order of[] a practitioner.” 21 U.S.C. § 802(10). Indeed, as the evidence shows, Barsoum required the CS to produce fictitious prescriptions in order to provide a paper trail which, in the event his pharmacy was inspected by the authorities, he could use to justify the distributions. In short each of the transactions was a blatant drug deal and a distribution in violation of the CSA. See 21 U.S.C. § 841(a)(1), 21 CFR 1306.04(a).

Accordingly, I hold that the Government has established that Registrant, through its principal Mr. Barsoum, committed acts which rendered its registration “inconsistent with the public interest,” 21 U.S.C. § 824(a)(4), and which justified the immediate suspension of its registration as “an imminent danger to the public health or safety.” Id. § 824(d). I therefore affirm the immediate suspension of Registrant’s registration, and while Mr. Barsoum allowed Registrant’s registration to expire, had he filed a renewal application, I would have revoked his pharmacy’s registration.

⁴ See also 21 CFR 1306.11(a) (“A pharmacist may dispense directly a controlled substance listed in Schedule II that is a prescription drug as determined under . . . 21 U.S.C. 353(b) . . . only pursuant to a written prescription signed by the practitioner,” except for in an emergency situation.).

Pursuant to 21 U.S.C. § 824(f), “[u]pon a revocation order becoming final, all . . . controlled substances” seized pursuant to a suspension order, “shall be forfeited to the United States” and “[a]ll right, title, and interest in such controlled substances shall vest in the United States upon a revocation order becoming final.” As the Agency has previously held, a registrant cannot defeat the effect of this provision by allowing its registration to expire. Meetinghouse Community Pharmacy, Inc., 74 FR 10073, 10074 n.5 (2009); RX Direct Pharmacy, Inc., 72 FR 54070, 54072 n.3 (2007). Registrant had the right to challenge the suspension order before the Agency but chose not to.

Accordingly, I declare forfeited to the United States all controlled substances that were seized pursuant to the Immediate Suspension Order, which have not been previously declared forfeited by the District Court in the Judgment and Sentence in United States v. Barsoum. I further hold that in the event the District Court’s Judgment and Sentence are vacated, any controlled substances which had been previously declared forfeited by the District Court, shall be forfeited to the United States.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 824(a) and (d), as well as 28 CFR 0.100(b), I affirm the Order of Immediate Suspension of Registration issued to S & S Pharmacy, Inc., d/b/a Platinum Pharmacy & Compounding. Pursuant to the authority vested in me by 21 U.S.C. § 824(f), as well as 28 CFR 0.100(b), I further order that all controlled substances seized pursuant to the Order of Immediate Suspension of Registration, which are not subject to forfeiture pursuant to the District Court’s Judgment and Sentence in United States v. Ihab “Steve” Barsoum, No. 8:11-CR-548-T-33MAP (M.D. Fla. Feb. 5, 2013), be, and they hereby

are, forfeited to the United States. This order is effective [Insert Date THIRTY DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Dated: September 8, 2013

Michele M. Leonhart
Administrator

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